



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

1984 OCT 12 PM 3:31

OCT 12 1984

Edward L. Steinberg, M.Sc., O.D.
Vice Chairman of the Board
Thompson Medical Company
919 Third Avenue
New York, NY 10022

Re: Docket No. 81N-0022/CP0008 and
Docket No. 76N-052N/CP0008

Dear Dr. Steinberg:

This is in response to your citizen petition dated September 18, 1984, and filed with the Dockets Management Branch on September 20, 1984. The petition requested that the administrative records for the OTC weight control drug products and the OTC nasal decongestant drug products rulemakings be reopened to include new data and information on phenylpropanolamine hydrochloride.

The agency considers your petition to be a "feedback communication" under the OTC Drug Review procedures. It has been placed in the public record but at this time will not be included in the respective administrative records unless these data directly influence or are used by the agency in making a decision on the status of phenylpropanolamine in the OTC weight control drug products or OTC nasal decongestant drug products proposed rule. Announcement of the "feedback policy" was first included in the FEDERAL REGISTER of September 29, 1981 (46 FR 47740), and further clarified in the FEDERAL REGISTER of April 1, 1983 (48 FR 14050). If the data are not used by the agency in preparing these proposed rules, the agency will include them in the administrative records for the respective rulemaking when the administrative records reopen during the comment period following publication of the respective proposed rule. In any event, you may rest assured that the data will be under active review by the agency.

Should you have any questions regarding this matter, please refer to the docket numbers noted above and submit all inquiries in triplicate to the Dockets Management Branch at the address to which you sent your petition.

Sincerely yours,

William E. Gilbertson, Pharm. D.
Director
Division of OTC Drug Evaluation
Office of Drug Standards
Center for Drugs and Biologics

76N-052N

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MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Dockets Management Branch (HFA-305)

DATE: OCT 12 1984

FROM : Director
Division of OTC Drug Evaluation (HFN-510)

SUBJECT: Material for Docket No. 76N-052N



The attached material should be placed on public display under the above referenced Docket No.



This material should be cross-referenced to Comment CP0008.



William E. Gilbertson, Pharm. D.

Attachment